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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,696	10/05/2006	Edith Gardiner	42-000400US	5276
22798	7590	03/27/2009	EXAMINER	
QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.			LI, RUIXIANG	
P O BOX 458				
ALAMEDA, CA 94501			ART UNIT	PAPER NUMBER
			1646	
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			03/27/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/572,696	GARDINER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26 January 2009.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 106, 107, 122, 125-128, 139, 151 and 152 is/are pending in the application.

4a) Of the above claim(s) 107, 122, 125-128, 139, 151 and 152 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 106 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 03/20/2006 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 01/27/2007 and 01/26/2009.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_.

## DETAILED ACTION

### *Restriction/Election*

1. Applicant's election with traverse of Invention Group I (claim 106) in the reply filed on 01/26/2009 is acknowledged. The traversal is on the ground(s) that modulators of Y receptor associated differentiation of an MSC or BMSC into an osteoblast-type cell or an adipocyte-type cell are linked and, therefore, the claims 106 and 107 share unity of invention. This is not found persuasive because they lack the same or corresponding special technical features because the special technical feature of Group I is considered to be a method of determining a compound that is a modulator of Y receptor associated differentiation of a mesenchymal stem cell or bone marrow stromal cell into an osteoblast-type cell comprising determining the number of differentiated osteoblast-type cells, whereas the special technical feature of Group II is considered to be a method of determining a compound that is a modulator of Y receptor associated differentiation of a mesenchymal stem cell or bone marrow stromal cell into an adipocyte-type cell comprising determining the number of differentiated adipocyte-type cells.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 106, 107, 122, 125-128, 139, 151, and 152 are pending. Claim 106 is currently under consideration. All other claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected

invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 01/26/2009.

***Information Disclosure Statement***

3. The information disclosure statements filed on 01/23/2009 and 01/12/2007 have been considered by the Examiner and a signed copy of the form PTO-1449 is attached to the office action.

***Drawings***

4. The drawings filed on 03/20/2006 are accepted by the Examiner.

***Claim Rejections—35 USC § 112, 1<sup>st</sup> paragraph***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 106 is rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation

necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claim 106 is drawn to a method of determining a compound that is a modulator of Y receptor associated differentiation of a mesenchymal stem cell (MSC) or a bone marrow stromal cell (BMSC) into an osteoblast-type cell. The claim is broad because it encompasses any Y receptors. The specification discloses that targeted disruption of the neuropeptide Y2 receptor results in increased bone volume, increased trabecular number and increased trabecular volume (Example 1). The specification also discloses that tissue specific targeted disruption of the neuropeptide Y2 receptor results in increased bone volume, increased trabecular number and increased trabecular volume (Example 2). The results of the study of the Y2<sup>-/-</sup> mice and the conditional Y2<sup>-/-</sup> mice in Examples 1 and 2 provides the evidence that hypothalamic Y2 receptors inhibit bone formation. The absence of detectable levels of Y receptors mRNAs in bone tissue provides evidence that this effect of Y2 deficiency occurs by a central mechanism (page 83, the 2<sup>nd</sup> paragraph of the specification).

However, the specification fails to provide supporting evidence showing that Y receptor activity modulates the differentiation of MSC or BMSC into an osteoblast-type cell. The specification discloses that osteoblast surface (Figure 7C), osteoblast

number (Figure 7D), osteoid surface, and mineralizing surface were all unaffected by hypothalamic Y2 receptor deletion (page 82, lines 18-20). The specification does not provide sufficient guidance, and/or working examples on how to make and use the claimed method to identify a compound that is a modulator of Y receptor associated differentiation of MSC or BMSC into an osteoblast-type cell. Example 12 merely discloses an assay on the effects of Y receptor deficiency on differentiation of MSC. The example does not show that Y receptor activity and/or expression modulates the differentiation of MSC or BMSC into an osteoblast-type cell.

The prior art teaches regulation of bone formation by hypothalamic Y2 receptors (Baldock et al., J. Clin. Invest. 109:915-921, 2002) and synergistic effects of Y2 and Y4 receptors on bone mass in double knockout mice (Mol. Cell Biol. 23:5225-5233, August 2003). However, the prior art does not teach that any Y receptor activity affects the differentiation of a MSC or BMSC into an osteoblast-type cell. One skilled in the art would first have to determine whether Y receptor activity modulates the differentiation of MSC or BMSC into an osteoblast-type cell in order to practice the claimed method.

Accordingly, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the instant invention.

***Claim Rejections—35 USC § 112, 2<sup>nd</sup> paragraph***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 106 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 106 is indefinite because it recites, in step (iii), "determining Y receptor activity and/or expression and the number of differentiated osteoblast-type cell...". The language is so ambiguous that the claim is indefinite.

### ***Conclusion***

9. No claims are allowed.

### ***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/  
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.  
March 23, 2009